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| APPLICATION NO.               | FILING DATE              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|-------------------------------|--------------------------|----------------------|---------------------|------------------|--|
| 10/801,207                    | 03/16/2004               | Bey-Dih Chang        | SEN-001US3          | 3124             |  |
| Keown & Asso                  | 7590 03/20/200<br>ciates | EXAMINER             |                     |                  |  |
| Suite 1200                    |                          | MARVICH, MARIA       |                     |                  |  |
| 500 West Cumr<br>Woburn, MA 0 |                          | ART UNIT             | PAPER NUMBER        |                  |  |
|                               |                          |                      | 1633                |                  |  |
|                               |                          |                      |                     |                  |  |
|                               |                          |                      | MAIL DATE           | DELIVERY MODE    |  |
|                               |                          |                      | 03/20/2008          | PAPER            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary   |   | Application No  |   | Applicant(s)   |             |  |  |  |
|---|---|---|---|--|-------------|--|--|--|
|   |   | 10/801,207  |   | CHANG ET AL.   |             |  |  |  |
|   |   | Examiner  |   | Art Unit   |             |  |  |  |
|   |   | MARIA B. MAR  | /ICH  | 1633   |             |  |  |  |
| The MAILING DATE of<br>Period for Reply   | this communication app  | pears on the cove   | r sheet with the c  | orrespondence ad   | ddress      |  |  |  |
| A SHORTENED STATUTOR WHICHEVER IS LONGER, F - Extensions of time may be available un after SIX (6) MONTHS from the mailing - If NO period for reply is specified above - Failure to reply within the set or extend Any reply received by the Office later th earned patent term adjustment. See 3'  | ROM THE MAILING D, der the provisions of 37 CFR 1.1 p date of this communication. e, the maximum statutory period ved period for reply will, by statute an three months after the mailing                         | ATE OF THIS CO<br>36(a). In no event, how<br>will apply and will expire<br>to cause the application | OMMUNICATION rever, may a reply be time SIX (6) MONTHS from to become ABANDONEI | I. lely filed the mailing date of this of (35 U.S.C. § 133). |             |  |  |  |
| Status  |   |   |   |  |             |  |  |  |
| 1)⊠ Responsive to commur  | nication(s) filed on 27 D   | ecember 2007  |   |  |             |  |  |  |
| 2a) This action is <b>FINAL</b> .   | · · ·   | action is non-fir   | al  |  |             |  |  |  |
| ′ <del>_</del>  | / <del></del>   |   |   | secution as to the   | a marite is |  |  |  |
| ,   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |   |   |  |             |  |  |  |
| closed in accordance w  | in the practice under 2   | -x parte Quayre,  | 1000 O.D. 11, 40  | 0.0.210.   |             |  |  |  |
| Disposition of Claims   |   |   |   |  |             |  |  |  |
| 4)⊠ Claim(s) <u>1,3,6-8 and 26</u>  | 6-37 is/are pending in th   | ne application.   |   |  |             |  |  |  |
| 4a) Of the above claim(   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |   |  |             |  |  |  |
| 5) Claim(s) is/are a  |   |   |   |  |             |  |  |  |
| · · · · · · · · · · · · · · · · · · ·   | 6)⊠ Claim(s) <u>1,3,6-8 and 26-37</u> is/are rejected.  |   |   |  |             |  |  |  |
| 7) Claim(s) is/are o  | -   |   |   |  |             |  |  |  |
| 8) Claim(s) are sub   | -   | r election require  | ement.  |  |             |  |  |  |
|   | ,   | ,   |   |  |             |  |  |  |
| Application Papers  |   |   |   |  |             |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |   |   |   |  |             |  |  |  |
| 10)⊠ The drawing(s) filed on :  | <u>3/16/04</u> is/are∶ a)⊠ ac   | cepted or b) 🗌 c  | bjected to by the   | Examiner.  |             |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |   |   |  |             |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |   |   |  |             |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |   |   |  |             |  |  |  |
| Priority under 35 U.S.C. § 119  |   |   |   |  |             |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |   |   |  |             |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-8 2) Notice of Draftsperson's Patent Dra 3) Information Disclosure Statement(s Paper No(s)/Mail Date  | awing Review (PTO-948)  | 4)<br>5)<br>6)  | Interview Summary<br>Paper No(s)/Mail Da<br>Notice of Informal Pa<br>Other:     | te   |             |  |  |  |

#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/07 has been entered.

Claims 1, 3, 6-8 and 26-37 are pending.

# Claim Objections

Claims 1, 8, 26, 31, 37 and 38 are objected to because of the following informalities: claim 1 recites "a compound that inhibits p21-induced senescence-associated changes in cellular gene expression" wherein the method is actually to identify -- a compound that inhibits p21-induced senescence-associated induction of cellular gene expression--.

Claims 6, 8, 29, 31, 35 and 37 recite "expression of the cellular gene is detected" whereas for accuracy in antecedent basis, the claim would be clearer if recited -- induction of the cellular gene is assayed--.

Claims 7, 30 and 36 recite "expression off the cellular gene is detected by assaying" whereas for accuracy the claim should be amended to recite --induction of the cellular gene is assayed by detecting--.

Claim 26 step c) recites "of a gene" whereas for grammatical accuracy it should be recited --if a gene --.

Claims 26, line 12 and 13 should be amended to recite, --the gene that is repressed-- and --the gene that is induced-- as it is customary to use the article "the" or the term "said" when referencing limitations previously recited. The same amendment should be made to claim 32, line 8 and 9. For the same reasons, claim 27, line 2 should be amended to recite --the cellular gene that is induced by p21-- and claim 32, line 4 to --the mammalian cell--.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 28 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.** 

Claims 3, 28 and 34 are drawn to genes that can be assayed for regulation by p21 as indicators of compounds that inhibit, promote or induce p21 induced senescence associated changes in cellular gene expression. Hence, the claimed "genes" are essential subject matter. However, the disclosure incorporates the sequence by reference to Genbank Accession numbers, which constitutes an improper incorporation of the essential subject matter. Secondly, the listed genes include "EST" sequences which are not genes but are fragments of genes and as such do not meet the written description requirement of the claims.

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The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The claims are drawn to essential subject matter that is not provided in the specification such that a person of skill in the art would recognize that applicants were in possession of the subject matter. It is not proper to incorporate it by reference to the non-patent literature. If there is a proper incorporation by reference in the application as filed the specification can be amended to recite the sequence. The court and the Board have repeatedly held (Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,18 USPQ2d 1016 (CA FC, 1991); Fiers v. Revel, 25 USPQ2d 1601 (CA FC 1993); Fiddes v. Baird, 30 USPQ2d 1481 (BPAI 1993) and Regents of the Univ. Calif. v. Eli Lilly & Co., 43 USPQ2d 1398 (CA FC, 1997)) that an adequate written description of a nucleic acid requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, irrespective of the complexity or simplicity of the method; what is required is a description of the nucleic acid itself. In this case, the sequences available at the tie of filing are required. GenBank Accession numbers are not indicative of sequences in a set space of time but rather are bookmarks for fluid amendment of sequences. Furthermore, EST sequences are not genes and as such do not represent the genes of claims 3, 28 and 34.

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Claims 1, 3, 6-8 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying compounds that inhibit p21 induced senescence associated changes in cellular gene expression or promote p21 induced senescence associated changes in cellular gene expression wherein the method comprises inducing p21 expression and senescence in a mammalian cell in the presence and absence of a compound followed by assaying the cell for expression of genes down-regulated and/or up-regulated by p21 wherein the compound is identified as an inhibitor of p21 induced senescence if the genes up-regulated by p21 are up-regulated to a lesser extent in the presence of the compound and wherein the compound is identified as a promoter of p21 induced senescence if the genes up-regulated by p21 are up-regulated to a greater extent in the presence of test compound or the genes down-regulated by p21 are down-regulated to a greater extent in the presence of p21, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Furthermore, claims 32-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **These are new rejections.** 

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a

conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to methods of identifying compounds that inhibit p21 induced senescence associated changes in cellular gene expression, promote p21 induced senescence associated changes in cellular gene expression and induce p21 induced senescence associated changes in cellular gene expression. Each of the methods requires that an agent or culturing conditions be used to induce p21 followed by gene expression analysis of cells in the presence and absence of a test compound. If a gene that is induced by p21 is induced to a lesser extent in the presence of the compound, the compound inhibits p21 induced senescence associated changes in cellular gene expression. If genes repressed or induced by p21 are repressed or induced in the presence of the compound, the compound promotes or induces p21 induced senescence associated changes in cellular gene expression.

The claims are unpredictable for a variety of reasons. First, the claims recite specifically, "assaying the mammalian cell in the presence of p21 expression". It appears that this step is intended upon limiting the method to those in which p21 mediated changes are induced. In this way, compound effects on the expression of these genes can be measured. However, the step of assaying the cell is further recited to be "detected using immunological reagent", "by assaying for an activity of the cellular gene product" and "by hybridization of cellular RNA to nucleic acid complementary to the cellular gene". In other words, the assay step is a step in which the cell is likely lysed for analysis of protein or nucleic acid components. It is not possible at this step to be linked to p21 expression. By attempting to require the cell to specifically require p21

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expression, the claim has been improperly modified to require this step during the assay component of the method. It would be proper for applicants to recite in step a), use of agents or culturing conditions --to induce p21 and p21 mediated senescence--.

Secondly, claim 32 is drawn to methods of identifying a compound that induces p21 induced senescence-associated changes in cellular gene expression of expression. However, the method does not identify inducers of p21 induced senescence changes in cellular gene expression. The agent or culturing conditions induce p21 which results in p21 induced senescence associated cellular gene changes. The addition of the culturing can increase or decrease the induction but do not in themselves contribute to the induction. To induce means to cause. If applicants intend that the compound can function to perpetuate or increase the induction, it is not clear how these claims differ from the steps of promoting which means to contribute to progress or growth.

The invention recites use of a broad group of therapies to lower a level of FHL1. Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of antagonists, the lack of adequate working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 8, 26, 27, 29, 31-33, 35 and 37 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fisher and Jiang (US 6,051,376; see entire document). **This rejection is maintained for reasons of record in the office action mailed 1/11/07 and 7/27/07 and restated below.** 

Fisher and Jiang propose methods of identifying inhibitors of senescence (see e.g. col 17, line 45-50). The methods involve culturing a plurality of cells with a compound and assaying for expression of MDA7 as a marker. Method of assaying includes using immunological agents and hybridization (see e.g. figure 4 and col 58, line 28-64). MDA7 it is taught is induced by induction of senescence (see e.g. col 98, line 8-30), which is also associated with induction of p21 or mda6 (col 109, line 25-38). Identification of an inhibitor of MDA7, through identification of muted MDA7 expression, results in identification of inhibitors of p21 and senescence inherently. As well, applicants teach that Fibronectin is assayed following induction of senescence (conditions of IFNβ and MEZ).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 8, 26-29, 31-35 and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher and Jiang (US 6,051,376; see entire document) in view of Porter et al (J Cell Physiology, 1992, pages 545-551; see entire document). **This rejection is maintained for reasons of record in the office action mailed 1/11/07 and 7/27/07 and restated below.** 

Applicants claim a method of identifying inhibitors of senescence by assaying for expression of fibronectin XO2761.

The teachings of Fisher and Jiang are described above and are applied as before except; Fisher and Jiang do not teach that Fibronectin I is assayed as a marker for inhibition of senescence.

Porter et al teach that human fibronectin (absent evidence to the contrary, this is Fibronectin I and as evidenced by XO2761) is assayed using SEN-1, SEN-2 and SEN-3 as markers of senescence (see e.g. abstract). Porter et al teach that SEN antibodies react with fibronectin from a variety of cells and are useful markers for senescence. Multiple species were assayed and the antibodies were found to be universal for a variety of fibronectins from human. XO2761 is distinguishable by being from human.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assay for inhibitors of senescence using the methods taught by Fisher and Jiang using Fibronectin I as a marker as taught by Porter et al because Fisher and Jiang teach that it is within the ordinary skill of the art to induce senescence and assay for induction of gene expression of senescence related genes and then to identify inhibitors of senescence and because Porter et al teach that it is within the ordinary skill of the art to use human fibronectin as a

marker for senescence detectable by SEN antibodies. One would have been motivated to do so in order to receive the expected benefit of ease of detection from a variety of cells coupled with the ease of detection demonstrated by Porter et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary,

there would have been a reasonable expectation of success to result in the claimed invention.

Claims 1, 6-8, 26, 27, 29-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher and Jiang (US 6,051,376; see entire document) in view of Beug et al (US 6,383,733; see entire document). **This is a new rejection.** 

Applicants claim a method of identifying inhibitors of senescence by assaying for activity of a cellular gene product.

The teachings of Fisher and Jiang are described above and are applied as before except; Fisher and Jiang do not teach that the assay uses a measure of gene product activity.

Beug et al teach culturing of a mammalian cell comprising a reporter gene fused to the plasminogen activator inhibitor promoter to induce senescence. Reporter gene expression was detected by assaying activity of the cellular gene product.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assay for inhibitors of senescence as in the methods of Fisher and Jiang using the assay of gene activity as taught by Beug et al because Fisher and Jiang teach that it is within the ordinary skill of the art to induce senescence and assay for induction of gene expression of senescence related genes and then to identify inhibitors of senescence and because Beug et al teach that it is within the ordinary skill of the art to assay activity of a cellular product as an

indication of a cellular event. One would have been motivated to do so in order to receive the expected benefit of ease of detection using reporter gene assays in which gene function is assayed. As well, it would have been of the ordinary skill in the art to substitute one known method for another given that both methods are well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

## Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 and 103 on pages of the amendment filed 10/26/07. Applicants' arguments regarding Beug et al are persuasive.

Applicants' arguments filed 10/26/07 have been fully considered but they are not persuasive as regards Fisher et al. Applicants argue that Fisher et al do not include conditions in which senescence and MDA7 are induced. The reference as a whole is directed to identifying compounds "inhibiting senescence comprising: a) incubating a plurality of cells with an appropriate amount of a compound; b) detecting the expression of mda-7, the inhibition of the expression of mda-7 indicating that the compound is inhibiting senescence". The disclosure teaches multiple ways to induce senescence "removal of DEX results in a shutdown of the T-antigen and loss of proliferative capacity and senescence (SENESCENT)" (see figure 43). In the examples, "mda-7 expression is detected in IMR90 cells grown for extended times in culture (OLD) and approaching senescence." All of these conditions are agents or culturing conditions under which senescence is induced. Hence, expression of mda-7, which is assayed, is a

consequence of conditions such as those described in col 42 that lead to senescence. This step is inherently and explicitly part of the method of Fisher et al.

## **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 6-8 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims. That is, claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, U.S. Patent No. 6, 706,491 and the instant claims recite a method comprising treatment of a mammalian cell such that p21 is induced (the instant claims recite that senescence is induced which is a p21 related event) and then assay for genes induced by p21 in the presence and absence of test compounds. The method of the instant claims identifies inhibitors of senescence, which is inherent in the method of U.S. Patent No. 6, 706,491 that identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from U.S. Patent No. 6, 706,491, then two different assignees would hold a patent to the claimed invention of U.S. Patent No. 6, 706,491, and thus improperly there would be possible harassment by multiple assignees.

Claims 1, 3 and 6-8 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38, 40, 44, 49-52 and 55-57 of copending Application No. 10/233,032.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are

generic to all that is recited in claims 28-37 and 58-63 of copending Application No. 10/233,032. That is, claims 28-37 and 58-63 of copending Application No. 10/233,032.anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, copending Application No. 10/233,032 and the instant claims recite a method comprising treatment of a mammalian cell such that p21 is induced (the instant claims recite that senescence is induced which is a p21 related event) and then assay for genes induced by p21 in the presence and absence of test compounds. The method of the instant claims identifies inhibitors of senescence, which is inherent in the method of U.S. application 10/233,032, which identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 10/233,032, then two different assignees would hold a patent to the claimed invention of 10/233,032, and thus improperly there would be possible harassment by multiple assignees.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3 and 6-8 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30, 32, 33, 52-55, 95-101, 103-105 and 107-115 of copending Application No.09/861925.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been

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obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims. That is, claims 25-30, 32, 33, 52-58, 95-101, 103-105 and 107-115 of copending Application No.09/861925 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, application 09/861,925 and the instant claims recite a method of identifying a compound that inhibits induction of genes using a cell comprising a gene induced by p21 under conditions that induce senescence. The method of the instant claims identifies inhibitors of senescence, which is inherent in the method of U.S. application 09/861925, which identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from 09/861925, then two different assignees would hold a patent to the claimed invention of 09/861925, and thus improperly there would be possible harassment by multiple assignees.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Response to Argument

It is acknowledged that applicants' will address the provisional obviousness double patenting rejections upon indication of allowable subject matter. However, until the recited claims are patented or a terminal disclaimer is filed, the claims remain rejected.

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Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-

0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD Primary Examiner

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/Maria B Marvich, PhD/

Primary Examiner, Art Unit 1633